#### **BEFORE THE**

#### FOOD AND DRUG ADMINSTRATION

# **ROCKVILLE, MD**

# PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY

#### AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

# **DOCKET NO. 02N-0278**

**APRIL 4, 2003** 

#### COMMENTS OF THE CARGO AIRLINE ASSOCIATION

# Communications with respect to these Comments should be addressed to:

Yvette A. Rose Vice President – Regulatory Affairs Cargo Airline Association 1220 19<sup>th</sup> Street, N.W., Suite 400 Washington, DC 20036 (202) 293-1030 (202) 293-4377 (fax) cargoair@aol.com

# SUBMITTED VIA ELECTRONIC MAIL:

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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

#### **BEFORE THE**

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# PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT DOCKET NO. 02N-0278

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#### COMMENTS OF THE CARGO AIRLINE ASSOCIATION

# I. INTRODUCTION

The Cargo Airline Association (hereinafter "CAA") is the nationwide trade organization representing the interests of the all-cargo air carrier industry. A current membership list is attached hereto. On February 3, 2003, the Food and Drug Administration (hereinafter "FDA") published a Notice of Proposed Rulemaking (NPRM) proposing a regulation that would require U.S. purchasers, importers or their agents to submit prior notice of the importation of food to the FDA. 68 Fed. Reg. 5428 (February 3, 2003). Comments are due to be filed on or before April 4, 2003. CAA respectfully submits the following Comments.

It is important to note that these regulations were issued to implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Bioterrorism Act, P.L. 107-88, 116 Stat. 662 (June 12, 2002) (hereinafter "Act"). This Act requires that the FDA promulgate final regulations regarding prior notice by December 12, 2003.

116 Stat. 670, §307(c). Therefore, the FDA is under significant pressure to promulgate an

extremely complex and comprehensive set of regulations that have the potential to impact not only the traditional food community that FDA deals with and regulates on a daily basis, but also consumers, importers, brokers, carriers and their agents, as well as the economy as a whole. As outlined in the following Comments, CAA is very concerned with the potential negative impact on the air cargo industry and the shipping customers we serve.

# II. THE ALL-CARGO AIR CARRIER INDUSTRY

The aviation industry and specifically the air cargo segment is an integral part of the U.S. economy. U.S. and international companies have come to rely on air transportation to maintain competitiveness in the global marketplace, and the industry's international cargo traffic has increased substantially over recent time. The all-cargo component of air cargo transportation is a major part of this system. As a result, any potential impact on the way in which any cargo, including food is transported by air must be examined with the unique needs of the all-cargo industry and its shipper customers in mind.

All-cargo transportation is provided by various types of operations, including aircraft specializing in heavy air freight and the integrated express carriers responsible for providing time-definite, door-to-door transportation of all types of cargo. Regardless of the type of air cargo service provided, speed and reliability are key elements of the air cargo business and especially the imported food marketplace. Indeed, many industry members offer money-back guarantees if delivery commitments are not met. Therefore, any delay or cancellations have a significant and direct impact on the air cargo carriers and the shipping public that the industry serves. With the advent of just-in-time inventory, shippers rely on the time-definite service

offered by air cargo carriers. A major user of the just-in-time concept is the food community, including fresh fish, perishable food items and pet food.

#### III. PRIOR NOTICE PROPOSED REGULATION

# a. Proposed Time Frame

CAA is extremely concerned with proposed regulation requiring prior notice by noon of the calendar day before the day of arrival of food being imported into the United States. This time frame is simply unattainable without dismantling a necessary system of international time-definite service required by shippers around the world. Next-day delivery would be virtually impossible from most areas of the world and shippers would no longer be able to depend on delivery in the expected time frames. It is inconceivable that FDA would intend such a result.

In order to speed the flow of information, FDA plans on developing a web-based system to allow for the electronic submission of information. However, even with electronic submission, such a time frame would directly negatively impact the key elements of the air cargo business, speed and reliability, and would severely jeopardize the needs of the global shipping community. Moreover, it is unclear that this pre-loading information would in any way enhance the security of the nation's food supply. The air cargo industry is subject to many regulatory requirements and employs many of its own efforts to ensure the security of imported food. The industry works closely with U.S. Customs and the Transportation Security Administration on a daily basis. FDA recognizes this fact when it states that it "seeks to minimize the submission of duplicative information." 68 Fed. Reg. 5434. Most of the requested information is already supplied to FDA through ACS as part of the U.S. Customs entry process. Furthermore, FDA has

access to some of the information through the FDA's own OASIS system. Therefore, CAA respectfully urges FDA to coordinate with Customs and use the currently provided advance information to satisfy any prior notice requirements in order to avoid duplicative requirements.

# b. FDA Prior Notice System

From a security perspective, CAA is concerned with the FDA Prior Notice System envisioned by the FDA. It is unclear whether the information submitted to the FDA through this system would be publicly available by law since it could be subject to FOIA. It is doubtful that any legitimate security function is being served by requiring advanced submission of information that can become available to the public. Also, by creating a web-based system CAA is concerned with protecting the database from computer hacking and fraud. For this reason, CAA strongly urges FDA use the information currently provided through ACS and OASIS.

# c. Business Practices would be Severely Impacted

FDA requests comments on how business practices for all operations could change as a result of the proposed regulations. 68 Fed. Reg. 5443. The negative impact on the flow of commerce and on the trade practices of the industry cannot be overstated. Requiring the proposed additional information as outlined in the NPRM would necessitate changes to the air waybill, the training of company personnel, programming changes to internal computer systems and time preparing more documentation. The cost to the industry would be unreasonable, given the limited enhancement to security.

#### d. Personal Use Exemption

The FDA's proposal specifically exempts certain food products from the prior notice Requirements – food products carried by an individual entering the United States as part of the individual's personal baggage that are intended for personal use. Air cargo carriers import food products for a variety of customers, commercial and non-commercial shippers included. Therefore, we assume that the "personal use" exemption would also apply to those food shipments intended for personal consumption or non-commercial use. With the advent of the internet, air cargo is used for a wide range of food shipments, some for non-commercial purposes. Furthermore, our members carry thousands of transborder food shipments consisting of one non-commercial shipper sending food to another non-commercial recipient (e.g., friend abroad shipping cookies to a friend in the U.S.). Those types of shipments should clearly be outside the scope of the prior notice requirement.

# IV. APPLICABILITY OF SECTION 307 TO AIR TRANSPORT SPECIFICALLY

Prior to issuing these regulations, FDA launched an extensive outreach program and held a series of constituent meetings to discuss the development of the regulations. CAA attended a meeting on August 15, 2002, where the FDA made a presentation regarding the Act's requirements and began the process of hearing initial concerns. At that meeting, the various Sections of the Act were discussed in detail and FDA addressed the applicability of each Section. With regard to the airline and air transport industry, including the all-cargo airlines, as we understand it, only Section 306 (Maintenance of Records) speaks directly to the **transport** of food (emphasis added). Section 306(b) authorizes FDA to establish requirements for the creation and maintenance of records by persons who transport food. However, the prior notice

rulemaking currently at issue has the potential to be inconsistent with existing air carrier transport practices and would virtually destroy the just-in-time concept employed by our shipping customers, as well as the services now demanded by our customers and offered by our members. While CAA supports the FDA's mission to protect the nation's food supply, CAA respectfully requests that FDA consider the scope and impact of any new requirements.

Moreover, if FDA elects to issue regulations implementing Section 306(b), the air cargo industry and CAA would be happy to submit any necessary information and provide FDA with industry comments.

# V. CONCLUSION

For the reasons stated above regarding the uniqueness of the all-cargo air carrier industry and especially the express portion of our membership, CAA cannot support submitting prior notice information in the proposed time frame. In conclusion, CAA is happy to work with FDA via a working group <sup>1</sup> to address our concerns outlined above. The unique nature of the all-cargo air carrier industry and all the members of that segment of the industry must be considered and the proposals balanced against the potentially drastic impacts on the flow of commerce.

Respectfully submitted,

Yvette A. Rose
Vice President – Regulatory Affairs
Cargo Airline Association
1220 19<sup>th</sup> Street, N.W., Suite 400
Washington, DC 20036
(202) 293-1030
(202) 293-4377 (fax)
cargoair@aol.com

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<sup>&</sup>lt;sup>1</sup> To be truly effective, any such working group should include all segments of the industry and the organizations that represent them.

# CARGO AIRLINE ASSOCIATION MEMBERSHIP LIST

Belleville, MI

# **ALL-CARGO AIRLINES**

\* Airborne Express Seattle, WA \* Atlas Air, Inc. Purchase, NY \* Emery Worldwide Redwood City, CA \* Evergreen International Airlines, Inc. McMinnville, OR \* Federal Express Memphis, TN \* United Parcel Service Louisville, KY Air Transport International Little Rock AR Capital Cargo International Orlando, FL DHL Airways, Inc. Chicago, IL First Air Gloucester, Canada Dulles, VA Gemini Air Cargo Northern Air Cargo Anchorage, AK

# AIRPORT ASSOCIATE MEMBERS

USA Jet Airlines. Inc.

Alaska International Airport System Anchorage, AK Columbia Metropolitan Airport Columbia, SC Dayton International Airport Dayton, OH FIDC/Fairbanks International Airport Fairbanks, AK Louisville International Airport Louisville, KY Memphis-Shelby County Airport Authority Memphis, TN Metropolitan Washington Airport Authority Washington, DC New Orleans International Airport New Orleans, LA Oakland International Airport Oakland, CA Reno/Tahoe International Airport Reno, NV Rickenbacker International Airport Columbus, OH

# **OTHER ASSOCIATE MEMBERS**

Airbus North America Holdings, Inc.

Aviation Facilities Company, Inc.

Bristol Associates, Inc.

Campbell-Hill Aviation Group

Harrow & Co.

Integrated Airline Services, Inc.

Keiser & Associates

Herndon, VA

McLean, VA

Washington, DC

Alexandria, VA

New Canaan, CT

Denver, CO

Oakland, CA

<sup>\*</sup> Member, Board of Directors